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Casimir Jones, S.C. 440 Science Drive Suite 203 Madison, WI 53711				
EXAMINER				
TON, THAIAN N				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/647,361

Applicant(s)

WEISS ET AL.

Examiner

Thaia N. Ton

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 12-21, 32-35 and 41-43 is/are pending in the application.
- 4a) Of the above claim(s) 14, 32 and 33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 12, 13, 16-21, 34-35, 41-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicants' Amendment and Response, filed 1/22/08, has been entered. Claims 1, 3, 12-21, 32-35 and 41-43 are pending; claim 22 is cancelled; claims 14, 32, 33 are withdrawn; claims 1, 3, 12, 13, 16-21, 34-35, 41-43 are under current examination.

The Weiss Declaration, filed 1/22/08 has been considered and is persuasive.

This action is non-final.

Claim Amendments

The Examiner notes that in Applicants' claim amendment, claim 15 is not present. For the sake of compact prosecution, the Examiner has proceeded with an examination on the merits. However, Applicants are advised to include claim 15 in response to this Office action.

Election/Restrictions

Claims 14, 32 and 33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 8/14/06.

Applicant's election without traverse of Group I (claims 1-3, 12, 13, 16-22, 34, 35 and 41-43) in the reply filed on 8/14/06 is acknowledged.

Color Drawings

Color photographs and color drawings are acceptable only for examination purposes unless a petition filed under 37 CFR 1.84(a)(2) is granted permitting their use as acceptable drawings. In the event that applicant wishes to use the drawings currently on file as acceptable drawings, a petition must be filed for acceptance of

the color photographs or color drawings as acceptable drawings. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and an amendment to the first paragraph of the brief description of the drawings section of the specification which states:

The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the U.S. Patent and Trademark Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings have been satisfied.

In the instant case, it appears that color drawings were filed with the instant application. Applicants are required to fulfill the requirements for color drawings as outlined above.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 12, 13, 16-21, 34-35, 41-43 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is maintained for reasons of record advanced in the prior Office action.

Enablement is considered in view of the Wands factors (MPEP 2164.01(A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art, predictability of

the art and the amount of experimentation necessary. All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Applicants' Arguments. Applicants argue that the claims, as amended, are enabled. In particular, Applicants argue that the methods result in selected cells that express a distinct collection of markers and characteristics, in particular that the cells are negative for CD34 and CD45 and positive for telomerase activity, can be expanded *in vitro*, and maintained in culture through repeated passages. See pp. 6-7 of the Response. Applicants argue that the claims are now amended, the compositions can comprise cells other than UCMS cells, and that the claims do not require any level of homogeneity of the cells. See p. 7, 2nd ¶. Applicants argue that the specification teaches that UCMS cells are isolated as enriched fraction that grows out from the cultured UCM and that the cells are selected following a low number of passages and the cells that float at 24 hours (non-adherent) are removed. Applicants point to the specification to show that populations resulting from selection are mostly, although not completely uniform. See p. 7 of the Response.

Applicants argue that that the presence of cKit expression in the cells fails to define the claimed cells, and that this appears to be a written description – not enablement – type of rejection, apps argue that this argument does not appear to be applicable to method claims, which merely claim a method of making a population of cells, without recitation of a particular homogeneity and that a particular level of homogeneity is not required to use the claimed invention. See pages 7-8 of the Response.

Response to Arguments. These arguments are not persuasive. Although Applicants have now amended the claims to recite certain characteristics of the cells, the absence of CD34 and CD45 merely provide guidance to show that the cells are not of the hematopoietic lineage (see p. 39, lines 21-23 of the specification). Applicants have stated that the resultant cell culture is not required to be

homogeneous. However, the specification does not provide guidance for an enabled use of heterogeneous cell populations. The specification provides a specific definition of a UCMS cell, which includes that this cell be capable of unlimited mitotic divisions and a UCMS cell can produce cells from any of the three germ layers or germ cells (see p. 19, lines 3-10). The uses that are contemplated in the specification are solely for UCMS cells, not heterogeneous populations, or compositions that comprise these cells. For example, pages 24-27 detail various uses of the cells, such as establishing transfection of the cells and producing banks of the cells. Pages 29-35 detail various uses of the UCMS derived cells, however, they do not discuss utilizing a composition comprising UCMS cells and other cells would be utilized in these uses. Applicants point to Example 6 to show that homogenous populations of UCMS cells can be isolate. This example fails to provide guidance for the characteristics of the homogenous population of cells such that one of skill in the art could readily use the claimed methods in order to identify these cells. The specification does not provide any guidance with regard to uses for heterogeneous populations of UCMS cells, and therefore, it would have required undue experimentation for one of ordinary skill in the art to practice the claimed invention.

Additionally, it is unclear from the specification if the umbilical cord matrix stem cells in the resultant culture could be identified by being negative for CD34/CD45, positive for telomerase activity, can be expanded *in vitro* and maintained in culture through repeated passages, because if the resultant culture contained different cell types, it is unclear which cell type has which (or all) of the claimed characteristics.

The Examiner maintains that although the specification teaches expression of various markers, such as c-kit or alkaline phosphatase, however, it appears that these cells were found in a heterogeneous population of cells, and it is unclear if these cells/colonies expressed both markers simultaneously. Thus, given it is

unclear if one particular cell, or a population of mixed cells expressed the claimed characteristics, it would have required one of skill to practice undue experimentation in order to determine which cell(s) would express the appropriate markers that would sufficiently arrive at obtaining a UCMS cell. The claims require obtaining UCMS cells. The method steps result in a heterogeneous population of cells that may include UCMS cells, but the characteristics recited by the claims are not clearly supported by the specification as being solely expressed by UCMS cells. Thus, the marker analysis the Examiner provided in the prior Office action is germane to the instant rejection, because there is no definitive identification of a particular cell type.

The Examiner further responds that the prior rejection, with regard to the heterogeneous nature of the cells is not misplaced, or unrecognized. The specification fails to provide guidance for UCMS cells as a particular cell type – and only provides guidance for this cell in a composition including other cells. Given that the particular markers and characteristics that are instantly claimed, as well as taught in the specification, are expressed in various cell types, it would have required one of skill in the art to practice undue experimentation to determine what type(s) of cells are encompassed by UCMS cells, because the markers that are identified to be expressed by the claimed cells are expressed in other cell types.

Certain embodiments require that the cells be capable of differentiation to cell types of all three germ layers (see, for example, claims 34 and 41). However, the specification fails to provide guidance to show that the UCMS cells are capable of these characteristics. Thus, one of skill in the art would have had to practice undue experimentation to make the claimed cells, and further, because the cells have not been sufficiently characterized, would have had to practice undue experimentation with regard to how to use the cells in any of the contemplated uses.

Written Description

Claims 1, 3, 12, 13, 16-21, 34-35, 41-43 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants argue that the claimed invention is described, particularly in view that the cells express a unique combination of makers, and thus, one of ordinary skill in the art can recognize that the inventors are in possession of the invention as claimed. Applicants argue that UCMS cells have been clonally isolated and described as “round, small and blast-like morphology.” Applicants further argue that the claims are not directed to any stem cell, only those with specified characteristics. See page 10 of the Response.

These arguments are not persuasive. The claims encompass a heterogeneous population of cells. There is no guidance in the working examples with regard to the particular, identifying characteristics of a UCMS cell, only to a population of cells which comprise UCMS cells (*i.e.*, a heterogeneous population of cells). Example 6 only provides morphology of the cells, and does not show that the cells have any of the characteristics that are required in the claims. Thus, the claims encompass heterogeneous populations of cells, wherein different cells could express the markers (or absence of markers) and other characteristics required by the claims. Accordingly, the as-filed disclosure fails to provide a written description for the claimed UCMS cells, and as such, there is no indication that Applicants had possession of the claimed invention. The Examiner further notes that Applicants’ arguments with regard to “isolating” the UCMS cells (p. 11 of the Response), the term “isolating” does not provide a reduction to practice with regard to the characteristics of a UCMS cell. In particular, the term “isolating” encompasses isolation from the source (umbilical cord matrix), for example. It is maintained that the specification fails to provide sufficient written description for the stem cells, as

instantly claimed. Certain embodiments recite that the cells are capable of differentiation into derivatives of endoderm, ectoderm or mesoderm (claim 34), but the disclosure fails to provide sufficient written description for this cell, in the context of the claimed invention. Accordingly, the as-filed disclosure fails to provide a written description for the claimed UCMS cells, and as such, there is no indication that Applicants had possession of the claimed invention.

Claim Rejections - 35 USC § 112

The prior rejection of claims 2, 17-22, 34, 35 and 42 under 35 U.S.C. 112, second paragraph, is withdrawn.

Claim Rejections - 35 USC § 102

The prior rejection of claims 3, 34 and 35 under 35 U.S.C. 102(a) as being anticipated by Mitchell *et al.* is withdrawn in view of the 1.132 Declaration filed by Mark Weiss who confirms that Aubrey M. Baughman and Mark A. Beerenstrauch were not involved with the inventive process relating to the claimed invention. See Declaration, #5.

The prior rejection of claims 3, 34, 35 under 35 U.S.C. 102(b) as being anticipated by Thomson is withdrawn in view of Applicants' amendments to the claims.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3, 34, 35 are rejected under 35 U.S.C. 102(b) as being anticipated by Purchio *et al.* (US Pat. No. 5,919,702, July 6, 1999)

Claim interpretation: The claims are interpreted as follows: the claims are directed to cultured cell isolates comprising umbilical cord matrix stem cells isolated from an umbilical cord matrix source of stem cells. The specification teaches that the UCMS cells of the instant invention are produced from Wharton's Jelly. Given that the claims do not require homogeneity, a culture of Wharton's Jelly would inherently and necessarily contain the UCMS cells of the instant invention. With regard to claim 34, which is directed to "purified" preparations of UCMS cells, the term "purified" does not require any degree or percent of purity, therefore, purification can encompass a heterogeneous culture of cells.

Purchio teach cultures of Wharton's jelly (see col. 10-11, #5.1) that can be cultured and expanded. Accordingly, because Purchio teach a culture of cells from the same source as the instantly claimed cell compositions, Purchio's culture would inherently contain the cell compositions and cultures as instantly claimed. Therefore, any properties claimed for the cells would also be necessarily present. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In *re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See *In re Ludtke*, *supra*. Whether the rejection is based on "inherency" under 35 USC 102, on "prima facie obviousness" under 35 USC 103, jointly or alternatively, the

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burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. In re Best, Bolton, and Shaw, 195 USPQ 430, 433 (CCPA 1977) citing In re Brown, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Thaian N. Ton whose telephone number is (571) 272-0736. The Examiner can normally be reached on Monday through Thursday from 7:00 to 5:00 (Eastern Standard Time). Should the Examiner be unavailable, inquiries should be directed to Peter Paras, SPE of Art Unit 1632, at (571) 272-4517. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the Official Fax at (571) 273-8300. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Thaian N. Ton/
Primary Examiner
Art Unit 1632